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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,801	08/24/2001	J. Bryan Jones	GC525-2D1	3593

5100 7590 11/26/2003

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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PALO ALTO, CA 94304

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,801	JONES ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/25/2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/2001* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants amendment of claims 1, 4, 5 and 10 in the Paper of 8/25/2003 is acknowledged. Claims 1-13 are still at issue and are present for examination.

Applicants' arguments filed in this same paper have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 24-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

Applicants filing of an information disclosure statement on 8/24/2001, a copy of which a new 1449 was submitted on 9/8/2003, is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection was stated in the previous office action as it specifically applied to claim1 (2-13 dependent on). In response to this rejection applicants have amended

claim 1 and state that based upon this amendment they desire reconsideration and withdrawal of the rejection.

This argument is not found persuasive for the reasons previously stated. Applicants amendment of claim 1 is acknowledged, however, changing the rejected claims language from "providing ..." to "modifying an enzyme thereby creating ..." does not correct the referred to deficiency previously pointed out in the previously in the claim.

As previously stated, the claimed invention is a method, this above recitations are unclear to the extent that by "providing" or "modifying an enzyme thereby creating" a chemically modified mutant enzyme, it is unclear if the act of "changing an amino acid to a cysteine residue" is a part of the claimed method or is the method merely directed at assaying a chemically modified mutant enzyme, that was previously prepared as such.

As previously stated, in the interest of advancing prosecution the claim has been interpreted as broadly as reasonably possible, which is such that the claimed method is directed to a method of assaying a "chemically modified mutant enzyme" which was not necessarily modified as a part of the claimed method, but merely provided as a part of the claimed method, which is interpreted as the method steps are directed to this provided chemically modified mutant enzyme". As such this portion of the claim is further interpreted as a product by process type of recitation, and the only portion of the recitation that has patentable weight are the limitations of the chemically modified mutant enzyme itself, not the process by which it was made. Thus the claim is interpreted as a method for screening chemically modified mutant enzymes for amidase

and/or esterase activity comprising : modifying an enzyme thereby creating a chemically modified mutant enzyme, wherein said chemically modified mutant enzyme has at least some cysteine residues that have been modified by replacing the thiol hydrogen with a thiol side chain, contacting the chemically modified mutant enzyme with a substrate for an amidase and/or a substrate for an esterase; and determining whether the chemically modified mutant enzyme exhibits amidase and/or esterase activity.

It is suggested that the incorporation of an active step of "changing an amino acid residue to a cysteine residue" as a part of the claimed method would overcome the above rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Mutus et al. (Biochem. Biophys. Res. Comm., Vol. 112, N0. 3, 941-947, 1983).

The rejection was stated in the previous office action as it applied to previous claims 1, 3, 4 and 10, and repeated below.

Mutus et al. teach the modification of acetylcholintesterase with the fluorescent thiol reagent S-mercuric-N-dansylcysteine and the measurement of the esterase activity

of this modified mutant enzyme (See above 112 2nd paragraph rejection). Thus, Mutus et al. anticipates claims 1, 3, 4 and 10.

In response to this rejection, applicants have amended claims 1, 4 and 10 and traverse the rejection as it applies to the amended claims. Applicants argue that the office has not provided a *prima facie* case of anticipation with respect to claim 1 (claims 3, 4, and 10 dependent on). Applicants submit that claim 1 recites "a chemically modified mutant enzyme with one or more amino acid residues ... replaced by cysteine residues..." and that Mutus do not teach such an enzyme. While this is acknowledged, applicants are reminded of the previous and above 112 second paragraph rejection in which applicants claim contains no active step in which the amino acid residues are changed to a cysteine, and as stated above as such the referred to portion of the claim is further interpreted as a product by process type of recitation, and the only portion of the recitation that has patentable weight are the limitations of the chemically modified mutant enzyme itself, not the process by which it was made. Thus claims 1, 3, and 4 remain rejected by Mutus et al. Claim 10 which was previously included in this rejection has been dropped from the rejection because applicants have amended the claim to include an active step in which a specific amino acid is chosen as a part of the claimed method.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh

11/24/2003